

**REMARKS**

Applicants acknowledge receipt of the Office Action mailed February 14, 2008.

In the Office Action, the Examiner rejected claims 1, 3, 5-7, and 9 under 35 U.S.C. § 102(b) as being anticipated by *Morita* (U.S. Patent No. 5,730,753); rejected claims 10-12 under 35 U.S.C. § 102(b) as being anticipated by *Hofert et al.* (U.S. Patent No. 4,203,446); rejected claim 2 under 35 U.S.C. § 103(a) as being unpatentable over *Morita*; rejected claim 4 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Bajaj et al.* (U.S. Patent No. 6,056,765); rejected claim 9<sup>\*</sup> under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Duchon et al.* (U.S. Patent No. 5,964,718); rejected claims 13-15, 17-19, and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*; rejected claim 16 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Bajaj*; and rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Duchon*.

By this Amendment, Applicants amend claims 1, 10, and 13, and cancel claims 6 and 18, without prejudice or disclaimer. Upon entry of this Amendment, claims 1-5, 7-17, and 19-37 will remain pending, with claims 24-37 withdrawn from consideration. Of the claims under examination, claims 1, 10, and 13 are independent.

The originally-filed specification, claims, abstract, and drawings fully support the amendments to claims 1, 10, and 13. No new matter has been introduced.

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\* Applicants submit that there appears to be a typographical error in the Office Action. It looks as if the Examiner intended to reject dependent claim 8, and not dependent claim 9, under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Duchon*. Applicants respectfully request that the Examiner correct this typographical error in the next communication.

Based on the foregoing amendments, Applicants traverse the rejections above and respectfully request reconsideration for at least the reasons that follow.

**I. 35 U.S.C. § 102(b) REJECTIONS**

Applicants traverse the rejection of claims 1, 3, 5-7, and 9 under 35 U.S.C. § 102(b) as being anticipated by *Morita*. Applicants respectfully submit that amended independent claim 1 patentably distinguishes over *Morita* at least for the reasons described below. Applicants further submit that the rejection of claim 6 has been rendered moot by the cancellation of claim 6.

In order to properly establish that *Morita* anticipates Applicants' claimed invention under 35 U.S.C. § 102, each and every element of each of the claims in issue must be found, either expressly described or under principles of inherency, in that single reference. Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." See M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

*Morita* appears to disclose an assembly for adjusting a pricking depth of a lancet including a cap element 3, an adjusting element 5, and a cover element 7. The cap element 3 includes a thread portion 17, and the adjusting element 5 includes a thread portion 53. The thread portion 53 is constructed such that it is engaged with a thread groove 47 of the thread portion 17 through a screw engagement mechanism. (*Morita*, col. 11, ll. 1-28 and col. 12, ll. 60-67).

*Morita*, however, does not disclose an interior nozzle comprising a ramped groove and an assembly groove, wherein a collar pin in a collar is configured to slide through the assembly groove to the ramped groove, as required by amended claim 1.

The Examiner asserts that *Morita* discloses the following claimed limitations: “a ramped groove (47)...; a collar pin (53)...; [and] an assembly groove (39)...” (*Office Action*, p. 6, line 9 - p. 7, line 10). The alleged collar pin 53, however, is not configured to slide through the alleged assembly groove 39 to the alleged ramped groove 47.

As disclosed in Applicants' specification at page 12, lines 13-14, and illustrated in FIG. 9 of Applicants' drawings, “to assemble the collar 50 and the interior nozzle 22, one can slide the collar pin 51 through the assembly groove 66 to the ramped groove 68.”

Accordingly, with respect to independent claim 1, *Morita* fails to teach Applicants' claimed combination, including, *inter alia*:

an interior nozzle comprising a ramped groove, a lancet wall,  
and an assembly groove;

a collar comprising a collar pin that engages the ramped  
groove and slides relative to the ramped groove, the collar  
being adapted to rotate relative to the interior nozzle;

wherein the collar pin is configured to slide through the  
assembly groove to the ramped groove (emphases added).

Since *Morita* fails to disclose each and every element of independent claim 1, *Morita* fails to anticipate claim 1, and claims 3, 5, 7, and 9 that depend from claim 1. Therefore, claims 1, 3, 5, 7, and 9 are patentable over *Morita*.

Applicants traverse the rejection of claims 10-12 under 35 U.S.C. § 102(b) as being anticipated by *Hofert*. Applicants respectfully submit that independent claim 10 patentably distinguishes over *Hofert* at least for the reasons described below.

*Hofert* appears to disclose a spring lancet holder for creating accurate standardized, reproducible puncture wounds in the skin for medical diagnostic purposes. (*Hofert*, Abstract). The spring lancet holder 10 includes a lancet 12 mounted within a collar 14, which is formed at one end of a blade guide 16, which is mounted for motion within a housing 18. The blade guide 16 may be moved vertically downward. Retarding this downward motion is a restoring spring 20. (*Id.* at col. 2, ll. 49-58).

*Hofert*, however, does not disclose an external compression spring comprising a first end and a second end, the first end comprising a reduced coil diameter that engages the one or more retaining features of the lancet holder, as required by claim 10.

The Examiner asserts that *Hofert* discloses “an external compression spring (20) comprising a first end and a second end (see the Figure), the first end comprising a reduced coil diameter that engages the one or more retaining features (14) of the lancet holder (16) as seen in the Figure...” (*Office Action*, p. 9, ll. 4-7). Applicants respectfully disagree.

The Examiner alleges that “the retaining features of 14 are internal where the lancet is mounted to...” (emphasis added). (*Office Action*, p. 9, line 1). Accordingly, it is not possible for the restoring spring 20 to engage with the alleged retaining features that are internal to where the lancet 12 is mounted.

As disclosed in Applicants' specification at page 10, lines 11-13, and illustrated in FIG. 5 of Applicants' drawings, “[t]he external spring 44 can engage the retaining features 36 of the lancet holder 34 and an end of the retainer 40. In an exemplary

embodiment, the diameter of the external spring 44 is reduced near where the external spring 44 engages the retaining features 36...”

Accordingly, with respect to independent claim 10, *Hofert* fails to teach Applicants’ claimed combination, including, *inter alia*:

an external compression spring comprising a first end and a second end, the first end comprising a reduced coil diameter that engages the one or more retaining features of the lancet holder (emphases added).

Since *Hofert* fails to disclose each and every element of independent claim 10, *Hofert* fails to anticipate claim 10, and claims 11 and 12 that depend from claim 10.

Therefore, claims 10-12 are patentable over *Hofert*.

## **II. 35 U.S.C. § 103(a) REJECTIONS - *Hofert* as Primary Reference**

Claims 13-15, 17-19, and 21-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*. Applicants respectfully disagree with the Examiner’s arguments and conclusions and submit that amended independent claim 13 patentably distinguishes over *Hofert* and *Morita* at least for the reasons described below. Applicants further submit that the rejection of claim 18 has been rendered moot by the cancellation of claim 18.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 6 (Sept. 2007). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See *id.* “A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention.” M.P.E.P. § 2145. Furthermore,

"[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art" at the time the invention was made. M.P.E.P. § 2143.01(III), internal citation omitted. Moreover, "[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." M.P.E.P. § 2141.02(I), internal citations omitted (emphasis in original).

"[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art." M.P.E.P. § 2141(II). "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." M.P.E.P. § 2141(III).

As amended, independent claim 13 recites an adjustable nozzle assembly, comprising "an interior nozzle comprising a ramped groove, an assembly groove, and a lancet wall; [and] a collar comprising a collar pin that engages the-ramped groove and slides relative to the ramped groove, the collar being adapted to rotate relative to the interior nozzle[,]. . . wherein the collar pin is configured to slide through the assembly groove to the ramped groove."

As discussed above, *Hofert* appears to disclose a spring lancet holder for creating accurate standardized, reproducible puncture wounds in the skin for medical diagnostic purposes. (*Hofert*, Abstract).

As admitted by the Examiner, “*Hofert* does not disclose an adjustable nozzle assembly.” (*Office Action*, p. 12, line 5). *Hofert* also fails to disclose or suggest “an interior nozzle comprising a ramped groove, an assembly groove, and a lancet wall; [and] a collar comprising a collar pin that engages the-ramped groove and slides relative to the ramped groove[,]...wherein the collar pin is configured to slide through the assembly groove to the ramped groove,” as recited in claim 13.

In order to cure the deficiencies of *Hofert*, the Examiner relies on *Morita* and alleges “*Morita* discloses all the features of the adjustable nozzle...” (*Office Action*, p. 12, line 6). As discussed above, *Morita* does not disclose an interior nozzle comprising a ramped groove and an assembly groove, wherein a collar pin in a collar is configured to slide through the assembly groove to a ramped groove. The Examiner asserts that *Morita* discloses the following claimed limitations: “a ramped groove (47)...; a collar pin (53)...; [and] an assembly groove (39)...” (*Office Action*, p. 6, line 9 - p. 7, line 10). The alleged collar pin 53, however, is not configured to slide through the alleged assembly groove 39 to the alleged ramped groove 47.

Accordingly, the elements of independent claim 13 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claimed invention. Accordingly, no reason has been clearly articulated as to why the claims would have been obvious to one of

ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 13, and claims 14, 15, 17, 19, and 21-23 which depend from claim 13. Claims 13-15, 17, 19, and 21-23 are therefore patentable over *Hofert* and *Morita*. Applicants request that the rejection of claims 13-15, 17-19, and 21-23 under 35 U.S.C. § 103(a) be withdrawn.

Claim 16 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Bajaj*; and claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Duchon*. The deficiencies of *Hofert* and *Morita* are discussed above.

With respect to *Bajaj*, the Examiner asserts that “Bajaj discloses that the detent (136 shown in Fig. 1 on component 104) forms a cantilevered portion of the collar ramp (Fig. 1)” (*Office Action*, p. 11, ll. 5-6); and with respect to *Duchon*, the Examiner alleges that “Duchon discloses that the contact surface (48) is concave...” (*Id.* at p. 11, ll. 16-17). Such teachings, even if present in *Bajaj* and *Duchon*, which Applicants do not concede, fail to cure the deficiencies of *Morita* and *Hofert*. Accordingly, claims 16 and 20 are patentable at least due to their dependence from independent claim 13.

### **III. 35 U.S.C. § 103(a) REJECTIONS - *Morita* as Primary Reference**

Claim 2 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Morita*; claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Bajaj*; and claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Duchon*.



As discussed above, *Morita* appears to disclose an assembly for adjusting a pricking depth of a lancet including a cap element 3, an adjusting element 5, and a cover element 7. The cap element 3 includes a thread portion 17, and the adjusting element 5 includes a thread portion 53. The thread portion 53 is constructed such that it is engaged with a thread groove 47 of the thread portion 17 through a screw engagement mechanism. (*Morita*, col. 11, ll. 1-28 and col. 12, ll. 60-67).

The Official Action alleges that *Morita* discloses the claimed invention with the admitted exception of “the location of the notches and the detents, where the notches are in the collar and not in the interior nozzle and the detents are in the interior nozzle not on the collar” (*Office Action*, p. 10, paragraph 12). The Examiner further admits that “*Morita* does not disclose that the detent forms a cantilevered portion of the collar ramp” (*Id.* at p. 11, ll. 3-4); and “*Morita* does not disclose that the contact surface is concave” (*Id.* at p. 11, ll. 14-15). Moreover, *Morita* does not disclose an interior nozzle comprising a ramped groove and an assembly groove, wherein a collar pin in a collar is configured to slide through the assembly groove to the ramped groove, as required by amended claim 1.

In order to cure the deficiencies of *Morita*, the Examiner relies on *Bajaj* and asserts that “*Bajaj* discloses that the detent (136 shown in Fig. 1 on component 104) forms a cantilevered portion of the collar ramp (Fig. 1)” (*Office Action*, p. 11, ll. 5-6), and relies on *Duchon* and alleges that “*Duchon* discloses that the contact surface (48) is concave...” (*Id.* at p. 11, ll. 16-17). Such teachings, even if present in *Bajaj* and *Duchon*, which Applicants do not concede, fail to cure the deficiencies of *Morita*. Specifically, *Bajaj* and *Duchon* fail to teach or suggest “an interior nozzle comprising a

ramped groove and an assembly groove, wherein a collar pin in a collar is configured to slide through the assembly groove to the ramped groove," as required by amended claim 1. Accordingly, claims 2, 4, and 8 are patentable at least due to their dependence from independent claim 1.

#### IV. CONCLUSION

Applicants respectfully submit that claims 1-5, 7-17, and 19-23 are in condition for allowance.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: May 12, 2008

By: \_\_\_\_\_



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